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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,269	04/22/2005	Rolando Perez Rodriguez	1667-68/AMK	9058

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EXAMINER	
FORD, ALLISON M	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
12/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,269	PEREZ RODRIGUEZ ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-14* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 2 (claims 9-14) in the reply filed on 14 August 2007 is acknowledged. The traversal is on the ground(s) that the restriction requirement is not proper because the elected claims depend from claims in Inventive Group 1, and claims in Inventive Groups 3 and 4 depend from elected claims. Additionally, Applicants argue the dependencies of the claims across multiple Inventive Groups will require overlapping subject matter to be searched, and thus there is no undue burden on the examiner to examine all claims. Still further, Applicants state they disagree with the assertion that claim 1 is anticipated or obvious as set forth in the restriction requirement, but provide no specific argument or reasoning. Applicants have requested rejoinder in the event that any of the elected claims are found allowable.

These arguments have been fully considered, but are not found persuasive. The instant application was filed under the provisions of 35 USC § 371, and as such is subject to PCT Rule 13 Unity of Invention. Under PCT Rule 13.1 an application is limited to a single invention or a group of inventions so linked as to form a single general inventive concept. In the restriction requirement of 28 June 2007 it was shown that Inventive Groups 1-7 did not share a special technical feature which provided a contribution over the prior art, and thus unity of invention was lacking between the Inventive Groups. Additionally, regardless of dependencies across multiple Inventive Groups, the special technical feature of each Inventive Group is clearly distinct, as set forth in the restriction requirement. Applicants' current arguments as to a lack of burden due to overlapping subject matter resulting and dependencies of claims across Inventive Groups are only considerations in applications filed under the provisions of 35 USC § 111(a), and thus are not applicable to the instant application. It is maintained that the instant Inventive

Groups do not share unity of invention, and therefore the requirement is still deemed proper and is made FINAL.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 371, which papers have been placed of record in the file. The instant application is a national stage entry of PCT/CU03/00012, filed 22 October 2003, which claims foreign priority to Cuban national application 239/2002 filed on 23 October 2002. A certified copy of the Cuban national application (in the Spanish language) has been received and entered into the application file.

Abstract

The abstract of the disclosure is objected to because it contains more than one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 9 is objected to because the claim should read, "...to growth in a serum- and protein-free media." Additionally, it is noted claim 9 depends from a non-elected claim. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Reiter et al (US Patent 6,100,061).

Applicants' claim 9 is directed to a mammalian cell line adapted to growth in a serum- and protein-free media. Claim 9 is determined to be a product-by-process claim, stating the mammalian cell line is obtained by the method of claim 3; claim 3 sets forth steps to adapt a cell line to serum- and protein-free conditions. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, unless the method of production imparts a unique structural feature to the product. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case the method of claim 3 does not affect the cell line, per se, as the method does not impart any patentable distinctions to the cell line. Therefore, any cell line adapted to growth in serum- and protein-free media anticipates claim 9.

Reiter et al discloses mammalian cell lines which are adapted to grow and express recombinant proteins in serum- and protein-free conditions (See Reiter et al, claims 1-12). Therefore the reference anticipates the claimed subject matter.

Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Keen et al (Cytotechnology, 1996).

Applicants' claims are directed to a mammalian cell line adapted to growth in a serum- and protein-free media. Dependent claims require the cell line to be a myeloma, specifically NS0 cells. Further dependent claims require the NS0 cells to contain sequences encoding for recombinant polypeptides or proteins, more specifically recombinant antibodies or fragments thereof. The claims are determined to be product-by-process claims, stating the mammalian cell line is obtained by the method of claim 3; claim 3 sets forth steps to adapt a cell line to serum- and protein-free conditions. Even though

product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, unless the method of production imparts a unique structural feature to the product. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case the method of claim 3 does not affect the cell line, per se, as the method does not impart any patentable distinctions to the cell line. Therefore, any cell line adapted to growth in serum- and protein-free media, with the claimed characteristics, anticipates the claims.

Keen et al disclose GS-engineered NS0 cell lines which are able to grow in serum-free and protein-free media (See Keen et al, abstract). Keen et al used NS0 cells which expressed CAMPATH-1H or humanized anti-CD2 monoclonal antibody, thus the cells contained sequences encoding for recombinant antibodies (See Keen et al, Pg. 208, col. 1, second full paragraph). Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen et al (Cytotechnology, 1996), in view of Crombet-Ramos et al (Int. J. Cancer, 2002, published online 27 August 2002), and further in view of Baker et al (Biotechnology and Bioengineering, 2001).

Applicants' claims are directed to a mammalian cell line adapted to growth in a serum- and protein-free media. Dependent claims require the cell line to be a myeloma, specifically NS0 cells. Further dependent claims require the NS0 cells to contain sequences encoding for recombinant

polypeptides or proteins, more specifically recombinant antibodies or fragments thereof, and more specifically the humanized recombinant antibody anti-EGF-R hR3 or a fragment thereof. The claims are determined to be product-by-process claims, stating the mammalian cell line is obtained by the method of claim 3; claim 3 sets forth steps to adapt a cell line to serum- and protein-free conditions. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, unless the method of production imparts a unique structural feature to the product. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case the method of claim 3 does not affect the cell line, per se, as the method does not impart any patentable distinctions to the cell line. Therefore, any cell line adapted to growth in serum- and protein-free media, with the claimed characteristics, anticipates the claims.

As set forth above, Keen et al disclose NS0 cell lines which are adapted to grow in serum- and protein-free media (See Keen et al, abstract). Keen et al states that production of antibodies and therapeutic proteins in fully defined (serum- and protein-free) media is desirable due to lower cost, better reproducibility, regulatory considerations and purification of the product (See Keen et al, Pg. 208, third full paragraph). Keen et al create NS0 cells which encode for CAMPATH-1H or humanized anti-CD2 monoclonal antibody; yet they do not disclose NS0 cells which product a humanized anti-EGFR antibody hR3. However, at the time the invention was made it would have been obvious to one of ordinary skill in the art to create NS0 cells encoding for any desired recombinant protein and subject them to the adaptation process of Keen et al.

At the time the invention was made, the humanized anti-EGFR antibody hR3 was recognized as a potential anti-cancer agent (See Crombet-Ramos et al, abstract), and thus production of this antibody was desirable.

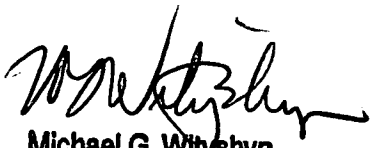
Therefore, one of ordinary skill in the art would have been motivated to engineer NS0 cells which encode for the humanized anti-EGFR antibody hR3, and to then subject the cells to the adaptation process of Keen et al to produce NS0 cells which are adapted to grow in serum- and protein-free media and which produce the anti-EGFR antibody hR3. One would have had a reasonable expectation of successfully engineering the NS0 cells to encode for the anti-EGFR antibody hR3 because the sequence was known in the art (See Crombet-Ramos et al), as well as methods to engineer NS0 cells; at the time the invention was made NS0 cells were recognized as a favored host cell type for production of therapeutic recombinant proteins (See Baker et al, abstract). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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